REMARKS

If the claims of the amendment filed on 2/7/2005 have not been entered, Applicants request that the 2/7/2005 amendment be entered, as the present amendment amends the claim language of that amendment.

Claims 9-20 have been deleted without prejudice to filing a divisional or continuation application. Claims 24-34 are presently canceled without prejudice. Claims 1 to 8 have been amended to address transdermal drug delivery compositions. The amendment is supported by the specification, for example, in the originally filed claims and the drawings. No new matter is added. Claim 1 has been amended to further clarify that the peptidic buffer buffers pH drift caused by electrotransport. Support for this amendment can be found, e.g., in the specification on page 21, lines 3-21. No new matter is added . New claims 35-39 have been added to address the inclusion of gelling agent in the composition. The new claims are supported by the specification, for example, on page 25 and Example 1. No new matter is added. Claims 1-8, 21-23 and 35-39 are pending.

Election/Restriction

The Examiner objected to the claims and asserted that since Applicants have received an action on the merits for the originally presented invention, Applicants' amendment of 8/4/2005, which amended the claims to address devices, was not fully responsive to the previous office action. It is noted that in the Office Action of 12/8/1999, the Examiner stated that claims 1-8 were drawn to one of the inventions: dipeptide containing compositions. In the present response, Applicants herein amended the claims to address polypeptide containing compositions, i.e., compositions for electrotransport delivery. Thus, withdrawal of the objection is respectfully requested.

Rejection Under § 112

In the Office Action of 2/4/2002, the Examiner has rejected claims 1-8 as being indefinite for failure to particularly point out and distinctly claim the subject matter that Applicants regard as the invention because the claims refer to "dipeptide buffer". The Examiner asserts that the claim is confusing as to how a dipeptide can contain 3-5 amino acids and still be a dipeptide.

Applicants have deleted the "dipeptide" term from the claims. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 102(b) or § 103(a) over Sorensen

The Examiner has rejected claims 1-8 under 35 U.S.C. § 102(b) as being anticipated or in the alternative being prima facie obvious over Sorensen WO 93/12812 (7/93). Applicants respectfully traverse the rejection.

It is submitted that Sorensen is entirely unrelated to transdermal drug delivery. There is nothing in the Sorensen document that will give guidance to a person skilled in the art on the property of an electrotransport reservoir for drug delivery. Further, although Sorensen might have given some examples of a formulation with a pH within 1 unit of the pI of dipeptide in the formulation, there are also other formulations with a pH not within 1 unit of the pI of dipeptide in the formulation and with pKa not the same as what is presently being claimed, among other differences. There is no teaching or suggestion by Sorensen to choose one over the other. Just because something narrower is present among a broader range of choices does not mean one would be motivated to choose a particular narrower choice. It is noted that Applicants have discovered that the pH and ionic properties of the reservoir render the peptidic buffer with peptide of particular pI's especially suitable for maintaining pH in the reservoir for long period of time to minimize skin irritation in electrotransport drug delivery. This is because the pH tends to drift as ions move away from the composition in transdermal delivery and the peptidic buffer reduces the pH drift. This relationship and combination of the properties of the polypeptides and the reservoir is one of the aspects of the novelty and nonobviousness of the present invention.

There is no indication that the Sorenson composition can have an ionic drug that is deliverable by electrotransport. Further, Sorenson is concerned about hormone stability and has nothing to do with minimizing pH drift in electrotransport of charged drug ions. Thus, the present invention is novel and nonobvious over Sorenson. What works for maintaining stability of material in storage does not mean it will work for connecting charges caused by a dynamic system under electrotransport. Thus, applicants respectfully submit that the obvious rejection is misplaced.

Applicants respectfully request the withdrawal of the § 102(b) and § 103(a) rejections.

Rejection under 35 USC § 103(a) over Bjorn

The Examiner has rejected claims 1-8 as being obvious over Bjorn, WO 97/39768. Applicants respectfully traverse the rejection.

It is noted that Bjorn does not teach having a polypeptide at a pH within 1 unit of the pI of the polypeptide. The Examiner asserted that in Example 1 at page 18 Bjorn shows such an embodiment. However, as the Examiner stated, the preparation in Example 1 contains L-His, which is not a polypeptide, and therefore does not fit the claimed element. Further, as Applicants' specification points out (e.g., p. 4, lines 23-26), His is unstable in aqueous solution. Just because Bjorn writes about different dipeptides (which may have different pI's) does not mean Bjorn gives any guidance on selection of pH to be within 1 unit of the pI of a polypeptide. Although Bjorn mentions a pH range of 6 to 8.8, there is no indication of choosing within that broad range a pH of within 1 unit of a pI of a polypeptide.

The Examiner asserts that optimization of pH and concentration in order to obtain optimum buffering capacity is within one skilled in the art. However, Bjorn's objective is to slow degradation of human growth hormone overtime. Applicants want to maintain pH for efficient electrotransport, which is an active transport system. What is useful for slowing degradation of growth hormone does not teach or suggest what is good for transdermal electrotransport of ionic drugs. By analogy, what makes a car sturdy against impact does not suggest that it would make the car run fast. One who wants a fast car will not look for guidance from a prior art car that is sturdy. Applicants have discovered that the pH and ionic properties of the reservoir renders the peptidic buffer with particular pI and pKa's particularly suitable for maintaining pH in the reservoir for electrotransport drug delivery. This relationship is entirely unrelated to and not mentioned by Bjorn. Similar to the absence of motivation discussed in the above related to Sorensen, there is also no motivation to select the particular narrow ranges of pKa, pI, pH, in relation to the electrotransport reservoir based on Bjorn. For an obviousness rejection, there must be some motivation or suggestion to choose and to modify a reference.

Since Bjorn does not mention any motivation to keep pH within 1 unit of pI of a polypeptide or the selection of particular pKa's, and their technology is entirely unrelated to electrotransport, there is no such motivation.

Further, in the newly added claims, the composition further comprises a gelling agent. It is submitted that the growth hormone compositions of Sorenson and Bjorn do not contain a gelling agent and do not suggest a gelling agent. The growth hormone compositions are to be delivered to a person and certainly gelling agents are undesirable in such compositions. Thus, the newly added claims are novel and nonobvious over the prior art.

Applicants respectfully request the withdrawal of the § 102(b) and § 103(a) rejections.

CONCLUSION

Applicants submit the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC 112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited.

Applicants believe that no fee is due with this communication. However, if it is determined that underpayment or overpayment has been made, the Director is authorized to debit or credit Deposit Account 10-0750, respectively.

Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

Respectfully submitted,

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